REMARKS

Upon entry of the foregoing amendment, claims 45-49 and 51-56 are pending in the application, with claim 45 being the independent claim. Claims 45, 51, 53 and 55 are sought to be amended. Claims 1-44 and 50 were canceled by previous amendment without prejudice to or disclaimer of the subject matter therein.

Claim 45 has been amended to delete the phrase "the growth of blood vessel tissues" and to insert in its place the phrase "hypertrophy of the vascular intima." Support for this change can be found in the specification as filed, e.g., in Example 6, on pages 40-41, in particular, at page 40, lines 14-15. Claim 45 has also been amended to replace "chimera" with "chimeric," as requested at page 2, lines 7-8, of the pending final Office Action. Claims 45, 51 and 55 have been amended to insert correct punctuation and to recite standard English-language syntax.

Claim 53 has also been redrafted into independent form to incorporate the elements of independent claim 45, from which claim 53 previously depended, with the exception that claim 53 as currently presented does not recite a chimeric antibody having a human antibody constant region.

The amendments to claims 45, 51, 53 and 55 have been made to put these claims into better form for consideration on appeal, as required under 37 C.F.R. § 1.116(b)(2). Amended claims 45, 51, 53 and 55 were not presented earlier because Applicants believed that they were allowable in their previous forms.

These changes are believed to introduce no new matter, and their entry is respectfully requested. Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claim 53 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement because, according to the Office, the claim includes impermissible new matter. (Office Action, at page 2, line 10, to page 3, line 5.)

Specifically, the Office contends that claim 45 (from which claim 53 depends) recites a method of administering antibodies "having a human antibody constant region," that claim 53 recites antibody fragments (e.g., Fab, scFv) that do not comprise a constant region, and

that there is no disclosure in the specification of Fab or scFv fragments that comprise a human constant region. (Office Action, at page 2, line 18, to page 3, line 1.)

To expedite prosecution and without acquiescing to the propriety of the rejection, Applicants have amended claim 53 to incorporate the elements of claim 45, with the exception of the element of a chimeric antibody having a human antibody constant region. Applicants submit that present claim 53 does not include new matter and request that this rejection be withdrawn.

Claims 45-49 and 51-56 are also rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. (Office Action, at page 3, lines 6-7.) Specifically, the Office contends that "the specification does not disclose a general inhibition of blood vessel growth by the claimed antibodies" and that "there is nothing in the specification or prior art to indicate applicants considered using the claimed antibodies to treat angiogenesis or neovascularization." (Office Action, at page 4, lines 3-4 and 9-11.)

To expedite prosecution and without acquiescing to the propriety of the rejection, Applicants have amended claim 45 to recite a method for suppressing hypertrophy of the vascular intima. Claims 46-49 and 51-56 also incorporate this amendment because they depend either directly or indirectly from claim 45.

The formation of new blood vessels, such as in angiogenesis or neovascularization, requires the building of a whole new vessel structure consisting among other things of smooth muscle cells and the intima (*i.e.*, endothelial cells and the elastic interna). Claim 45 as currently presented recites a method for suppressing hypertrophy of the vascular intima and does not encompass suppression of angiogenesis and neovascularization, which involves the formation of new blood vessels. The suppression of growth of vascular intima tissue is shown and described in the specification, e.g., in Example 6, at pages 40-41 of the specification as originally filed.

Applicants believe that one of skill in the art would reasonably believe that Applicants had possession of the invention as presently claimed at the time of filing of the application. Accordingly, Applicants submit that claims 45-49 and 51-56 comply with the written description requirement and request that this rejection be withdrawn.

Applicants believe that the rejections of claims 45-49 and 51-56 under 35 U.S.C. § 112, first paragraph (written description), have been overcome and request that these rejections be withdrawn.

Claims 45-49 and 51-56 are further rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement, because the specification, while being enabling for using humanized α-TF antibodies that prevent the activation of Factor X by a complex of TF/Factor VII to suppress restenosis, allegedly does not reasonably provide enablement for using such antibodies to suppress any other type of blood vessel growth, e.g., angiogenesis or neovascularization. (Office Action, at page 5, line 4-8.)

As discussed above, to expedite prosecution and without acquiescing to the propriety of the rejection, Applicants have amended claim 45 to recite a method for suppressing hypertrophy of the vascular intima, e.g., restenosis. Present claim 45 does not encompass suppression of angiogenesis and neovascularization, which involves the formation of new blood vessels. As claims 46-49 and 51-56 depend either directly or indirectly from claim 45, they also recite a method for suppressing hypertrophy of the vascular intima. Because the suppression of growth of vascular intima tissue is shown and described in the specification, e.g., in Example 6, at pages 40-41 of the specification as originally filed, Applicants submit that the specification fully enables present claims 45-49 and 51-56.

Applicants believe that the rejection of claims 45-49 and 51-56 under 35 U.S.C. § 112, first paragraph (enablement), has been overcome and request that this rejection be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 102

Claims 45-49 and 52 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Wong et al., U.S. Pat. No. 5,986,065 ("Wong"). (Office Action, at page 7, lines 16-17.) Applicants respectfully traverse this rejection.

Specifically, the Office contends that Wong teaches TF-specific antibodies that bind human TF and inhibit the activation of Factor X by a TF/Factor VIIa complex, and can be used for treatment of, e.g., restenosis. (Office Action, at page 7, lines 21-23.)

Applicants submit that Wong fails to teach the method of suppressing hypertrophy of the vascular intima in a patient as recited in claims 45-49 and 52, because Wong describes the prevention of thrombosis and blood clotting only.

Hypertrophy of the vascular intima, e.g., restenosis, involves the formation of new blockages at the side of angioplasty or stent placement. There are two major mechanisms to distinguish for restenosis. The first one is thrombosis, which is the greatest threat immediately after angioplasty. Thus, giving anti-clotting medicine makes only sense during or shortly after the surgical intervention. The second form of restenosis is tissue growth at the site of treatment. The tissue growth is a proliferation of the endothelial cells which tend to occur during the first 3-6 month after the procedure and is not prevented by anti-clotting drugs. It is understood as an overgrowth of tissue inside the artery wall. This overgrowth is a formation of scar tissue and happens in some people as a result of the artery healing process.

Wong describes the use of TF antibodies as short-term active thrombosis medicaments only. Nothing is mentioned or suggested in Wong with respect to the use of such antibodies for the purpose claimed in present patent application. This is because the influence of inhibitory TF-antibodies on the proliferation of intima tissue was not known until the present invention was made. The use of such antibodies to suppress the cell growth of intima tissue is therefore new and inventive over the cited state of the art.

Applicants thus submit that because Wong fails to teach the claimed method of suppressing hypertrophy of the vascular intima in a patient, Wong does not anticipate the present claims.

Applicants believe that the rejection of claims 45-49 and 52 under 35 U.S.C. § 102 has been overcome and request that this rejection be withdrawn.

III. Claim Objections

Claim 45 is objected to because "chimera" in line 6 of the claim should allegedly be "chimeric." The Office requests appropriate correction. (Office Action, at page 2, lines 7-8.)

To expedite prosecution and without acquiescing to the propriety of the objection, Applicants have amended claim 45 to replace "chimera" with "chimeric" at line 6 of the

claim. Accordingly, Applicants believe that the objection to claim 45 has been overcome and request that this objection be withdrawn.

IV. Information Disclosure Statement

Submitted with the present amendment is a copy of IL 85411, a foreign patent cited in the Information Disclosure Statement filed in this application on March 29, 2002, which reference was crossed through and not initialed or considered by the Examiner. A copy of this foreign patent, which was cited in the corresponding International Search Report, was not found in the Image File Wrapper of the present application. Applicants note that all of the other foreign and literature references cited in the International Search Report are found in the Image File Wrapper.

A copy of the unconsidered reference has now been provided. Therefore, applicants respectfully request that the reference be considered by the Examiner and be made of record in the present application, and that an initialed copy of Form PTO/SB/08 filed on March 29, 2002, be returned in accordance with MPEP §609.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date October 1, 2008

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